DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 28, 2015

CAScination AG
Mr. Matthias Peterhans
Chief Executive Officer
Stauffacherstrasse 78
CH-3014 Bern
Switzerland

Re: K143024
Trade/Device Name: CAS-One Liver system
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OEW
Dated: March 19, 2015
Received: March 23, 2015

Dear Mr. Peterhans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143024

Device Name
CAS-One Liver system

Indications for Use *(Describe)*
The CAS-One Liver system is indicated for open liver surgical procedures where image guidance may be appropriate and where the patient can tolerate long apneic periods under general anesthesia

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

CASCINATION
Stauffacherstrasse 78
CH-3014 Bern
Switzerland

510(k) Summary

Manufacturer:	CAScination AG
Contact:	Matthias Peterhans CEO Stauffacherstrasse 78 CH-3014 Bern Switzerland Tel: +41 31 832 5182 Email: matthias.peterhans@cascination.ch
Date Prepared:	2015-04-28
Trade Name:	CAS-One Liver system
Common Name:	A navigation system for open liver surgery
Classification Name:	Stereotaxic Instrument (21 CFR 882.4560)

Description:

The CAS-One Liver system is indicated for open liver surgical procedures where image guidance may be appropriate and where the patient can tolerate long apneic periods under general anesthesia. It visualizes the position and pose of surgical instruments relative to a three-dimensional model of the patients liver in real-time.

Step 1 – Preoperative Imaging

Preoperatively a bi- or tri-phasic CT scan or an MRI scan of the patient is acquired and processed using a virtual surgery planning tool (MeVis Medical Solutions, Bremen, Germany).

Step 2 – Virtual Surgery Planning

The processing includes segmentation of relevant anatomical or pathological structures of the liver (intrahepatic vessels, tumors, segments and the liver surface). The segmentation then enables calculation of patient-individual vascular territories for each vessel system and identification of vascular branches affected by different treatment strategies. The patient-individual 3D models provide support in analyzing the remaining functional liver volume and associated risks with different resection or ablation strategies towards an optimized patient-specific operative strategy.

Step 3 – Intraoperative Setup

Prior to the surgical procedure, all components of the system are set up close to the OR table. The 3D model is then loaded into the navigation software. Using the navigation system, the model can be zoomed, rotated and its different sub-models can be displays according to the surgeon's needs. Sterile draping of the device and assembly of the sterile instrumentation is performed. The computer displays a 3D model of the present anatomical situation, a plan of the surgical strategy and a view of the available ultrasound images.

Step 4 – Planning

After surgical preparation of the liver, a complete examination of the liver can be performed by palpation and intra-operative ultrasound. For preparation of the navigated procedure an area of interest for navigation or a set of anatomical landmarks is selected on the touch screen. The navigation system stores their positions and uses them for registration.

Step 5 – Registration

The registration procedure requires a few seconds and can be repeated whenever necessary. Registration is either based on navigated intra-operative ultrasound or on landmark points acquired with navigated surgical instruments.

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Stauffacherstrasse 78
CH-3014 Bern
Switzerland

Step 6 – Resection/Ablation Guidance

The computer system displays a 3D model of the liver anatomy, the resection/ablation plan, and a view of the available ultrasound images on a monitor near the operative field. This provided continuous real-time feedback and enables for the guidance of the surgical instruments towards the planned treatment locations (resection planes or ablation targets).

Indications for Use:

The CAS-One Liver system is indicated for open liver surgical procedures where image guidance may be appropriate and where the patient can tolerate long apneic periods under general anesthesia.

Substantial Equivalence:

CAS-One Liver system exhibits characteristics that are similar or the same as the selected predicate device. The following predicate device was selected:

– Pathfinder Therapeutics, Inc. EXPLORER Liver - Passive Tracking [K101979]

The predicate device was shown to have the same indications for use and intended use. A comparison of the following key technological characteristics was also performed between the predicate and subject devices:

– Marker Shields: Attaches to surgical instruments to passively track them for navigation
– Instrument Sensing: This is the method in which the system detects the surgical instruments
– Instrument Navigation: This shows the position and orientation of the instruments with respect to the preoperative 3D patient model
– Calibration: The means of calibrating the surgical tools to the preoperative patient 3D model.
– Registration: The method of aligning the preoperative patient data with the patient organ.
– Fusion Ultrasound: This technology overlays preoperative patient data with other views of data.
– 3D Patient Preoperative Data: A visual representation in 3D of the patient preoperative data.
– Ultrasound: An ultrasound device, integrated or externally connected, which provides ultrasound images of the patient.

This analysis identified the following minor technological characteristic differences between the subject and predicate devices:

– Method of sterilization
– Materials used for attachments
– Fusion Ultrasound
– Use of simulated ablation volume
– Registration method with pointing device
– Materials used for shields

As these differences related to technology implementation choices, reference devices were selected for further comparison analysis:

- Perfint Healthcare. Pvt. Ltd. MAXIO [K132108]
- BrainLAB AG Cranial IGS System [K082060]

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CH-3014 Bern
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- Brainlab AG Image guided Surgery System [K083310]
- Symmetry Surgical Universal Ring Deaver Retractor Blade [Exempt – 878.4800]
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Performance data was also submitted to further demonstrate safety and effectiveness.

An evaluation of the above information concluded that the CAS-One Liver system is substantially equivalent.

Biocompatibility

All devices of the CAS-One Liver system have the following patient contacting characteristics:

- External Communicating Devices
- Blood path indirect
- Limited (<24h)

These components were assessed for their biocompatibility through their adherence to material standards and appropriate testing according to ISO 10993.

Electrical Safety

Electrical safety tests according to IEC 60601-1:2005/A1 2012 and IEC 60601-1-2:2007 were conducted on the CAS-One Liver system and the system was found to conform.

Software Verification and Validation

Through risk management, the software was classified as having a moderate level of concern as a latent flaw in the software would result in minor injury to the patient. Verification and validation testing appropriate to the software classification was carried out.

Bench Testing

Bench testing to show the accuracy and reproducibility was conducted and shown to meet the defined acceptance criteria for various functionality of the system (such as calibration, tracking and registration).

Conclusion

The above performance testing and substantial equivalence to predicate and reference devices shows that the CAS-One Liver system is safe and effective for its intended use.